FDA-designated personnel to examine at reasonable times and in a reasonable manner all relevant financial records and sales data of the sponsor and manufacturer.

[57 FR 62085, Dec. 29, 1992, as amended at 78 FR 35133, June 12, 2013]

§ 316.22 Permanent-resident agent for foreign sponsor.

Every foreign sponsor that seeks orphan-drug designation shall name a permanent resident of the United States as the sponsor's agent upon whom service of all processes, notices, orders, decisions, requirements, and other communications may be made on behalf of the sponsor. Notifications of changes in such agents or changes of address of agents should preferably be provided in advance, but not later than 60 days after the effective date of such changes. The permanent-resident agent may be an individual, firm, or domestic corporation and may represent any number of sponsors. The name of the permanent-resident agent, address, telephone number, and email address shall be provided to: Office of Orphan Products Development, Food and Drug Administration, Bldg. 32, rm. 5271, 10903 New Hampshire Ave., Silver Spring, MD 20993.

[78 FR 35133, June 12, 2013]

§ 316.23 Timing of requests for orphan-drug designation; designation of already approved drugs.

(a) A sponsor may request orphan-drug designation at any time in its drug development process prior to the time that sponsor submits a marketing application for the drug for the same rare disease or condition.

(b) A sponsor may request orphan-drug designation of an already approved drug for an unapproved use without regard to whether the prior marketing approval was for a rare disease or condition.

[78 FR 35133, June 12, 2013]

§ 316.24 Deficiency letters and granting orphan-drug designation.

(a) FDA will send a deficiency letter to the sponsor if the request for orphan-drug designation lacks information required under §§ 316.20 and 316.21, or contains inaccurate or incomplete information. FDA may consider a designation request voluntarily withdrawn if the sponsor fails to respond to the deficiency letter within 1 year of issuance of the deficiency letter, unless within that same timeframe the sponsor requests in writing an extension of time to respond. This request must include the reason(s) for the requested extension and the length of time of the requested extension. FDA will grant all reasonable requests for an extension. In the event FDA denies a request for an extension of time, FDA may consider the designation request voluntarily withdrawn. In the event FDA considers a designation request voluntarily withdrawn, FDA will so notify the sponsor in writing.

(b) FDA will grant the request for orphan-drug designation if none of the reasons described in § 316.25 for requiring or permitting refusal to grant such a request applies.

(c) When a request for orphan-drug designation is granted, FDA will notify the sponsor in writing and will publicize the orphan-drug designation in accordance with § 316.28.

(d) A sponsor may voluntarily withdraw an orphan-drug designation request or an orphan-drug designation at any time after the request is submitted or granted, respectively, by submitting a written request for withdrawal to FDA. FDA will acknowledge such withdrawal in a letter to the sponsor. Any benefits attendant to designation (such as orphan-exclusive approval) will cease once designation is voluntarily withdrawn, from the date of FDA's acknowledgement letter. If a sponsor voluntarily withdraws designation, FDA will publicize such withdrawal in accordance with § 316.28.

[57 FR 62085, Dec. 29, 1992, as amended at 78 FR 35133, June 12, 2013]

§ 316.25 Refusal to grant orphan-drug designation.

(a) FDA will refuse to grant a request for orphan-drug designation if any of the following reasons apply:

(1) The drug is not intended for a rare disease or condition because:

(i) There is insufficient evidence to support the estimate that the drug is intended for treatment of a disease or